IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

Trans-Radial Solutions, LLC, ***Plaintiff*,** **v.** **Burlington Medical, LLC *et al.*,** ***Defendants*.**	**Civil Action No. 2:18-cv-00656**

PLAINTIFF'S RULE 72 OBJECTION TO MAGISTRATE JUDGE'S RULING EXCLUDING CERTAIN EXPERT OPINIONS OF DR. KENNETH GALL AND DR. JENNIFER VANDERHART

Plaintiff Trans-Radial Solutions, LLC ("TRS"), by counsel, pursuant to Fed. R. Civ. P. 72, objects to three portions of the Magistrate Judge's ruling excluding certain expert opinions of Dr. Kenneth Gall and Dr. Jennifer Vanderhart from trial. *See* D.E. 200. Specifically, TRS objects to the following holdings as clearly erroneous and contrary to law:

1. The Magistrate Judge's holding that, "Dr. Gall may not offer his projections for Rad-Guard's hypothetical market penetration and lost future sales because those projections are not based on any reliable data or method, and because he otherwise lacks the necessary qualifications, education, training, and experience to opine generally on lost future sales of the product." D.E. 200 at 1.

2. The Magistrate Judge's holding that Dr. Vanderhart may not testify to her lost future sales calculations and present value calculations that derive from Dr. Gall's improperly excluded opinions. *See* D.E. 200 at 2.

3. The Magistrate Judge's holding that, with respect to TRS's Cardio-Trap product, TRS will have to present evidence at trial other than Burlington's own sales projections to support "the precise number of units [Dr. Vanderhart] claims could have been sold." D.E. 200 at 3.

Because these rulings conflict with Fourth Circuit case law and introduce a high likelihood of a second trial after appeal, TRS respectfully asks the Court to correct or clarify the rulings.

Standard of Review

Under Rule 72, the district judge "must consider timely objections" to a magistrate judge's order on a nondispositive pretrial matter, "and modify or set aside any part of the order that is clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a).

Background

This case involves two patented products invented by TRS, the Rad-Guard® radiation shield and the Cardio-TRAP® radial access catheterization system.[1] TRS hired Burlington to market and sell its two products. Burlington and the other Defendants instead copied the Rad-Guard in order to create, market, and sell their own competing product, at a time most critical to the Rad-Guard's market introduction (as Burlington's CEO stated in deposition, "you only launch a product once"). At the same time, they suppressed sales of the more expensive Cardio-Trap, instructing their sales force to back-shelf it in hopes that TRS would flounder as a company.

TRS identified Dr. Gall, a physicist with 30+ years of experience in all aspects of buying, selling, studying, using, and launching radiation protection products, to evaluate the evidence and opine on the impact of Defendants' actions.[2] Dr. Gall first opines that Defendants' copycat product infringes TRS's patent, an opinion which the Magistrate Judge held he is qualified to render. Dr. Gall next opines on TRS's loss of market share by determining how many Rad-Guards would have been sold during the affected time frame "but for" Defendants' actions. The Magistrate Judge's order excluding this part of Dr. Gall's report is the central issue in this objection.

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[1] These two products are described in detail in TRS's motion for summary judgment and in other briefing in the case.

[2] A copy of Dr. Gall's curriculum vitae is attached as **Exhibit A**. Copies of his reports are attached as **Exhibits B and C**.

Based in part on Dr. Gall's analysis, TRS's damages expert, Dr. Vanderhart, a Ph.D. economist with 20+ years of experience in economic evaluation, quantified TRS's damages.[3]

Defendants did not identify any experts to rebut either of TRS's experts.

Dr. Gall's market share analysis

1. Market share "but for" Defendants' actions.

Dr. Gall begins his analysis by defining the relevant market for the Rad-Guard. The primary market is the U.S. cardiac catheterization (cath lab) market, consisting of approximately 2,000 labs as of 2018.[4] **Exhibit B** at p. 22. He also notes that "sizeable additional sales of the Rad-Guard® shield could be expected beyond the primary market," including the secondary U.S. market and international markets. *See id.* at pp. 22-23, 25. For the secondary U.S. market, Dr. Gall identifies at least 25 additional interventional radiology procedures. *See id.* at pp. 22-23.

Next, he explains why it is reasonable to expect significant market demand. He describes the functional benefits of the product, including how it solves better than any other product "the problem of reducing radiation exposure of support personnel who need to perform functions at or near a medical device hanger or IV pole while radiation is present." *Id.* at pp. 8, 24 ("no other product provides the same benefits"); *see also* **Exhibit C** at p. 6. As he summarized in deposition, the Rad-Guard "addresses a problem that everybody has in these cardiac catheterization labs. And when you see the way that it's intended to be used, and recognized the needs that the customers have, *you can recognize that it will have essentially a universal appeal to all of those customers*." D.E. 108-5 at 137:23-138:5l (emphasis added).

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[3] A copy of Dr. Vanderhart's curriculum vitae is attached as **Exhibit E**. A copy of her report is attached as **Exhibit F**.

[4] Dr. Gall provided Defendants a copy of a journal article from the American College of Chest Physicians that confirmed this number.

Third, he describes how the Rad-Guard fits within "the decision-making process that a hospital or medical facility would undergo in deciding to purchase" the product. **Exhibit B** at p. 24. Importantly, he also explains how hospitals "replace major medical equipment within a ten year timeframe," such that "the vast majority of major medical equipment such as cath lab suites will be replaced in a ten year cycle." *Id.* at p. 22. "It is therefore reasonable to assume that 100% of the addressable market will become available within a ten year timeframe." *Id.*

Fourth, he describes the increase in radiation concerns amongst the medical community as a further reason why customers would need the product, including how "the general practice of ALARA (subjecting radiation workers to As Low As Reasonably Achievable) doses, would be a compelling reason to purchase the Rad-Guard." *Id.* at pp. 24-25.[5]

Lastly, he describes TRS's patent and explains how there essentially are no acceptable non-infringing substitutes. *See id.* at p. 25 ("the patent protection providing for little meaningful competition").[6] The term of a patent is 20 years, *see* 35 U.S.C. § 154, or two replacement cycles for cath lab suite equipment.

For all these reasons, Dr. Gall concludes that, "but for" Defendants' actions, the Rad-Guard "could reasonably capture close to 100% of its Total Addressable Primary Market within a timeframe of 10 years." **Exhibit B** at p. 25.

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[5] ALARA is a requirement that all radiation safety programs must implement. 10 C.F.R. § 20.1101. It "means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest." 10 C.F.R. § 20.1003.

[6] This is also how Burlington touted the Rad-Guard when it first launched, emphasizing to customers that the Rad-Guard was (until Defendants introduced their copycat) "The ONLY Radiation Protective Solution that attaches to any standard IV pole." D.E. 151-12.

2. Reduced market share as a result of Defendants' actions.

Dr. Gall also opines that it is reasonably certain Defendants' actions have both decreased and delayed the maximum possible market penetration for the Rad-Guard. As a result of Defendants' interference with sales of the Rad-Guard and introduction of their inferior product into the marketplace, Dr. Gall opines that TRS will be able to capture no more than 70% market share, and it will take at least two procurement cycles to do so. *See id.* at pp. 25-27.

He supports this opinion in multiple ways using his knowledge, skill, and experience in the industry. First, he identifies the considerable problems that the Rad-Guard now faces as a result of Defendants' actions. *See id.* at p. 25. This is supported by ample evidence of Defendants' interference with the Rad-Guard's market launch and replacement of the Rad-Guard (for the same customer base) with their infringing product, *see, e.g.*, D.E. 151; sworn testimony of Burlington's CEO about the critical importance of a seamless product launch, *see* **Exhibit D** at 36:17 ("[Y]ou only launch a product once"); and evidence of the inferior quality of Defendants' product, which he expounded upon in his deposition. D.E. 114-09 at 146:21-147:13.

Second, Dr. Gall describes the two principle ways market performance will be impacted:

- "It would take considerably longer for the Rad-Guard® shield to saturate the market, since confusion in the marketplace over the origin, quality, and performance of the product will cause customers to hesitate to commit to a purchase. This can cause a delay of a full equipment replacement cycle, doubling the time to market saturation." **Exhibit B** at p. 26.

- "The percentage of the primary market that could be reached will be diminished, since some customers will have decided not to consider a product [the infringing IV Mounted Barrier] that has underperformed relative to their expectations or the expectations of colleagues who have shared their experiences." *Id.*

Third, he presents a new market penetration scenario that reflects his judgment as to the most likely market performance of the Rad-Guard after Defendants' actions; *i.e.*, that the product

should expect to penetrate no more than 70% of the primary market, and take a second 10-year hospital procurement cycle to achieve that result. *Id*.

Fourth, he provides support for the reduction to 70% as neither the most optimistic scenario nor the least optimistic scenario: "The most optimistic scenario would include sales outside the United States as well as sales to interventional radiology suites providing the variety of procedures list above and could assume a faster recapture of market penetration as well as increase in market saturation percentage." *Id*. Likewise, "the least optimistic scenario would be essentially flat with a low volume of stagnant sales resulting from loss of goodwill in the marketplace caused by the confusion and poor performance of the inferior competing products." *Id*. He further confirms the appropriateness of the 70% figure in deposition testimony as based on the factors above and his considerable experience in the industry. *See* D.E. 114-09 at 139:23-141:14 and 142:24-144:12.

Lastly, he provides support for the additional 10-year delay, as it corresponds exactly to the missed opportunity to achieve full penetration during a single hospital equipment procurement cycle. **Exhibit B** at p. 26.

The Magistrate Judge's order excluding Dr. Gall's market share opinions

The Magistrate Judge granted in part and denied in part Defendants' motion to strike Dr. Gall's testimony. D.E. 200. The Magistrate Judge correctly declined to strike Dr. Gall's infringement opinions, but incorrectly ruled that, "Dr. Gall may not offer his projections for Rad-Guard's hypothetical market penetration and lost future sales because those projections are not based on any reliable data or method, and because he otherwise lacks the necessary qualifications, education, training, and experience to opine generally on lost future sales of the product." *Id.* at p. 1. In support of this holding, the Magistrate Judge stated:

> Dr. Gall's personal involvement in the design and marketing of a complex radiation therapy system which sold for $28 million per unit provides no basis for his opinion for future sales of the Rad-Guard device which sold for less than $1,000.00. His anecdotal reference to two other products during his deposition did not appear to inform his disclosed expert opinion on future sales of the Rad-Guard as he was unable to offer any documentation or evidence related to either product or to any other similar product which might support his hypothetical projections.

Id. at pp. 1-2.

ARGUMENT

I. The Magistrate Judge's order excluding Dr. Gall's market opinions contradicts Rule 702 and controlling case law.

While district courts have "considerable leeway" in evaluating expert witnesses, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999), neither of the Magistrate Judge's conclusions regarding Dr. Gall's market share opinions is consistent with controlling law.

1.

There is no plausible way that Dr. Gall's opinions should be excluded for lack of reliable data or methods. The Magistrate Judge's opinion is silent on his reasoning for this point, except to say that Dr. Gall's "anecdotal reference to two other products during his deposition did not appear to inform his disclosed expert opinion on future sales of the Rad-Guard as he was unable to offer any documentation or evidence related to either product or to any other similar product which might support his hypothetical projections." D.E. 200 at pp. 1-2. The error in this statement is obvious: *that is not the basis for Dr. Gall's opinions*. These are issues the Defendants raised in their attempt to attack the weight and credibility of Dr. Gall's opinions.

The Magistrate Judge's analysis overlooks the actual bases for Dr. Gall's opinions, which he reliably combined with his considerable experience to arrive at his projections. This is exactly what an expert witness is supposed to do. *See* Fed. R. Evid. 702; *see also Kumho Tire*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based

on extensive and specialized experience."). Under controlling law, "questions regarding the factual underpinnings of [an expert's] opinion affect the weight and credibility of the witness' assessment, *not its admissibility*." *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017) (emphasis added).

The Fourth Circuit addressed this very situation just three years ago in *Bresler*, where both the district court and the Court of Appeals rejected the same argument that the Magistrate Judge accepted here. In *Bresler*, a dispute over trust funds, the plaintiff identified an expert to testify to lost future income, specifically, "the present value of an investment mechanism," including crediting rates, and the "current valuation of underfunding" certain insurance policies. *Id*. at 190. Just like here, the defendants challenged the expert on *Daubert* grounds, disputing his projections for future values that he then incorporated into his calculations.

Both the district court and the Fourth Circuit rejected the *Daubert* challenge. As the Fourth Circuit held, "Wilmington's *Daubert* challenge amounts to a disagreement with the *values Pugh chose to assign to certain variables*, including the cost of insurance and future interest rates." *Id*. at 195. Those variables, of course, were the *essence* of his expert opinion. The Fourth Circuit continued: "While Wilmington may have preferred that Pugh use higher costs of insurance in his formula, along with other values more favorable to Wilmington, Pugh's failure to do so did not require the district court to exclude Pugh's opinion under *Daubert*." *Id*. (distinguishing *Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 143 (4th Cir. 1994)).[7] The Fourth Circuit

[7] Tellingly, the *Tyger Construction* case that the Fourth Circuit distinguishes is the very case that Defendants rely on here. *See* D.E. 108 at p. 9; D.E. 129 at p. 7; *Tyger Constr.*, 29 F.3d at 143 (where expert witness said there was no available sand in a quarry, but there was undisputedly sand in the quarry, district court abused its discretion in admitting the expert's opinion).

concluded, "Rather, such challenges to the accuracy of Pugh's calculations 'affect the weight and credibility' of Pugh's assessment, *not its admissibility*." *Id*. at 195-96 (emphasis added).

In this case, better than in *Bresler*, multiple facts and data support Dr. Gall's opinions as set forth in his reports. None of them was given any credence by the Magistrate Judge.

As noted above, Dr. Gall's first opinion is that the Rad-Guard would have penetrated near 100% of the U.S. cath lab market over the course of 10 years "but for" Defendants' actions. *See* **Exhibit B** at pp. 22-25. No part of this opinion depends on Dr. Gall's "personal involvement in the design and marketing of a complex radiation therapy system which sold for $28 million per unit" or the "two other products" discussed in his deposition. Instead, numerous other factors go into this opinion, all of which are supported:

- First, he defines the specialized market that the Rad-Guard was designed to serve, including the primary cath lab market, the secondary market, and international sales.
- Second, he cites the unique nature of the Rad-Guard product itself. *Id*. at p. 22.
- Third, he identifies the patent protection of the product, "providing for little meaningful competition." *Id*. at p. 25.
- Fourth, he identifies the need for the Rad-Guard product in the market, including increased concern over radiation exposure in recent years. *Id*. at pp. 12-15, 24-25.
- Fifth, he identifies the tendency in this specialized market to gravitate toward standards of practice, or to single products that help a hospital system adhere to the mandatory principles of ALARA radiation exposure. *Id*. at p. 24; *see also* 10 C.F.R. § 20.1003.
- Sixth, he identifies the time scale of market penetration, supported by his 30+ year personal experience in the very market that would purchase the Rad-Guard; *i.e*., a single 10-year hospital equipment procurement cycle. *Id*. at p. 22.
- Seventh, he identifies the primary market size; *i.e*., the approximately 2,000 U.S. cath lab suites, each with more than one procedure room on average. *Id*. at p. 22.
- Eighth, he identifies the number of Rad-Guards each cath lab likely would purchase during its 10-year equipment procurement cycle; *i.e*., 5 units on average over 10 years, which is supported by, among other things, the spreadsheet he attaches to his report showing Burlington itself sold 8 of its infringing product to a single hospital system in just 3 years (New Hanover Regional Medical Center). *Id*. at p. 22 and Ex. 5.

- Ninth, he identifies the specific hospital budgeting and purchasing practices that support his opinion. *Id.* at p. 24.

All these facts underpin Dr. Gall's conclusion that the Rad-Guard would have achieved near 100% market penetration over the course of a 10-year hospital procurement cycle, but for Defendants' actions. The Magistrate Judge's order is silent as to what part of this is unreliable.

There is equal support for Dr. Gall's second opinion that Defendants' actions have decreased and delayed the maximum possible market penetration for the Rad-Guard, as shown from a complete reading of his report:

- First, he identifies the considerable problems that the Rad-Guard now faces as a result of the Defendants' actions. *Id*. at p. 25.

- Second, he describes the two principle ways the market performance will be impacted: (1) "It would take considerably longer for the Rad-Guard® shield to saturate the market, since confusion in the marketplace over the origin, quality, and performance of the product will cause customers to hesitate to commit to a purchase. This can cause a delay of a full equipment replacement cycle, doubling the time to market saturation," and (2) "The percentage of the primary market that could be reached will be diminished, since some customers will have decided not to consider a product [the infringing IV Mounted Barrier] that has underperformed relative to their expectations or the expectations of colleagues who have shared their experiences." *Id*. at p. 26.

- Third, he presents a new market penetration scenario that reflects his judgment as to the most likely performance of the Rad-Guard after the Defendants' actions – *i.e*., that the product should expect to penetrate no more than 70% of the same market, and take a second 10-year hospital procurement cycle to achieve that result. *Id*.

- Fourth, he provides support for the reduction to 70% as neither the most optimistic scenario nor the least optimistic scenario: "The most optimistic scenario would include sales outside the United States as well as sales to interventional radiology suites providing the variety of procedures list above and could assume a faster recapture of market penetration as well as increase in market saturation percentage." *Id*. Likewise, "the least optimistic scenario would be essentially flat with a low volume of stagnant sales resulting from loss of goodwill in the marketplace caused by the confusion and poor performance of the inferior competing products." *Id*.

- Fifth, he confirms the appropriateness of the 70% figure in deposition testimony as based on the factors above and his considerable experience in the industry. *See* D.E. 114-09 at 139:23-141:14, 142:24-144:12.

- Sixth, he provides support for the additional 10-year delay, as it corresponds exactly to the missed opportunity to achieve complete market penetration during a single hospital equipment procurement cycle. **Exhibit B** at p. 26.

This is far more support than that provided by the expert witness in *Bresler*, whose opinions the Fourth Circuit approved. Dr. Gall's methodology of combining that factual support with his 30+ years' experience to reach his ultimate 100% and 70% market share opinions over 10- and 20-year timeframes is exactly what Rule 702 permits: the combination of experience with other knowledge, skill, training, and education to provide a reliable foundation for expert opinion. *See* Fed. R. Evi. 702; *see also Kumho Tire*, 526 U.S. at 156; *Bresler*, 855 F.3d at 195-96. That Defendants disagree with Dr. Gall is the reason for cross-examination at trial. *Id.*

Because the Magistrate Judge's order is clearly erroneous and contrary to law, TRS respectfully asks this Court to correct the error. Under the analysis applied just three years ago in *Bresler*, exclusion of Dr. Gall's market opinions will likely lead only to a second trial.

2.

The Magistrate Judge's secondary reasoning is also clearly erroneous. It should be a rare event that an expert with 30+ years' experience in exactly the field at issue is excluded for lack of qualification. "Generally, *the test for exclusion is a strict one*, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is offered." *RG Steel Sparrows Point, LLC v. Kinder Morgan Bulk Terminals, Inc*., 609 F. App'x 731, 738-39 (4th Cir. 2015) (emphasis added) (quoting *Thomas J. Kline, Inc. v. Lorillard, Inc*., 878 F.2d 791, 799 (4th Cir. 1989)).

"Rule 702 was intended to liberalize the introduction of relevant expert evidence." *Id.* (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). The only basis offered by the Magistrate Judge for his conclusion that Dr. Gall is not qualified to opine on lost

market share is that, "Dr. Gall's personal involvement in the design and marketing of a complex radiation therapy system which sold for $28 million per unit provides no basis for his opinion for future sales of the Rad-Guard device which sold for less than $1,000.00." D.E. 200 at p. 1.

Yet Dr. Gall is not offered as an expert because he successfully launched a $28 million product. That information was supplied by Defendants. Dr. Gall is offered as an expert because he has spent more than three decades in the very system in which the Rad-Guard would be sold, on all sides of the product market. *See* **Exhibit A**. As indicated in his curriculum vitae and reports, Dr. Gall's unique expertise in this market derives from, among other things, his role as Chief of Physics and director of radiological medicine involved in procurement of radiation protection products at multiple hospitals, his personal experience working in interventional radiology suites with radiation protection devices, his personal experience marketing radiation therapy treatment systems, his personal development of marketing plans for new radiological products, his personal experience with the sale of patented products (he holds 14 patents in this field), and his consulting work for startup medical device manufacturers seeking access to national hospital markets.

The Magistrate Judge's isolated focus on Dr. Gall's experience with multi-million-dollar products ignores all this other experience, particularly Dr. Gall's role in hospital procurement. It also ignores all of Dr. Gall's consulting work assessing market conditions for radiological product lines, including devices that sell for thousands of dollars, not tens of millions. *See, e.g.*, D.E. 108-5 at pp. 18-19 (example of complete business startup proposal for Chinese company evaluating U.S. markets). Dr. Gall's expertise in this market thus derives not only from his background as the founder and CEO of a medical equipment company, to which the Magistrate Judge's order refers, but also his substantial experience in projecting sales and participating in purchasing radiation protection equipment for hospitals, all of which is relevant to his market share analysis.

Under Rule 702 and controlling Fourth Circuit law, Dr. Gall is highly qualified to opine on likely market penetration for the Rad-Guard product here. *See* Fed. R. Evi. 702; *see also RG Steel*, 609 F. App'x at 738-39. Excluding his market opinions on either basis offered by the Magistrate Judge will be clear error.

II. The Magistrate Judge incorrectly excluded Dr. Vanderhart's lost sales and lost investment value opinions based on his incorrect exclusion of Dr. Gall's opinions.

The Magistrate Judge also erred in excluding portions of Dr. Vanderhart's Rad-Guard calculations that rely on Dr. Gall's market opinions. Dr. Vanderhart calculated two key aspects of Rad-Guard damages based on evidence of per-unit profit and Dr. Gall's market share analysis: (i) present value of lost sales (that is, the 30% of sales that will never occur now), or $910,810, and (ii) lost investment value (pre-judgment interest) associated with the 10-year procurement cycle delay in market penetration, or $914,829. She also calculated other direct losses, such as lost profits due to Defendants' infringing sales.

The Magistrate Judge held that Dr. Vanderhart can testify to all the direct losses, but excluded her opinions "on lost Rad-Guard profits derived from future sales" because they "derive[] exclusively from Dr. Gall's Rad-Guard market projections which are unreliable." *Id.* at p. 2.

Because the Magistrate Judge's ruling with respect to Dr. Gall's market opinions is clearly erroneous and contrary to law, the Magistrate Judge's ruling with respect to Dr. Vanderhart's opinions is likewise clearly erroneous and contrary to law.

III. The Magistrate Judge incorrectly held that TRS must present additional evidence to support Dr. Vanderhart's calculations of Cardio-Trap damages.

The Magistrate Judge's holding with respect to Cardio-Trap damages is also contrary to law in one narrow sense. With respect to the Cardio-Trap, Dr. Vanderhart calculated $344,603 in damages due to Defendants' suppressed sales for a single year. She based this on evidence of per-unit profit and Burlington's own statements as to projected sales. *See* **Exhibit F** at pp. 18-27.

The Magistrate Judge held that, "if the trial court finds based on other testimony and evidence that Burlington had some ongoing duty to actively market and sell the Cardio-Trap (a contested point) and other evidence supports a quantity of lost future sales, Dr. Vanderhart's credentials and research support her precise calculations of per unit revenue and profit figures attributable to that loss." D.E. 200 at p. 3. "However, her selective citation to opinions of sales representatives is insufficient – standing alone – to support any continuing obligation by Burlington to market the product, or the precise number of units she claims could have been sold." *Id.* at p. 3-4.

TRS does not contest that it must show Burlington's obligation to market the Cardio-Trap, which it will do at trial. Nonetheless, the District Court should clarify or overrule this part of the Magistrate Judge's order, because a plaintiff does not have to (1) produce evidence beyond a defendants' own projections of future sales or (2) prove future damages with precision.

Neither Defendants nor the Magistrate Judge cite any legal authority to support this holding. Characterization of the sales team's projections as "selective citation" is contrary to the facts. The sales team's projections are proper evidence of likely future performance. In fact, Burlington's CEO confirmed in deposition that the company did not have formal sales forecasts or financial projections for the Cardio-Trap to establish otherwise. *See* **Exhibit D** at 52:5-10 ("Q. Did Burlington have any sales forecasts for either product? A. I'm not aware of any sales forecasts. Q. Were there any financial projections at all for these products? A. I have not seen any."). Moreover, a plaintiff need not prove damages with precision, but only with "reasonable certainty." *See Preferred Sys. Solutions, Inc. v. GP Consulting, LLC*, 284 Va. 382, 399-400 (2012) ("Claims for compensatory damages – in this case, lost profits – must be proved with reasonable certainty. The standard of review for a damages calculation has been framed as whether there were 'sufficient

facts' to support the award…. Damages are not rendered uncertain because they cannot be calculated with absolute exactness. It is sufficient if a reasonable basis of computation is afforded.") (international citations and quotation marks omitted). To hold TRS to a higher standard at trial – whether from an evidentiary standpoint or damages standpoint – will introduce unnecessary error, a result that the Magistrate Judge does not appear to have intended.

CONCLUSION

WHEREFORE, because there is no basis to strike any part of Dr. Gall's or Dr. Vanderhart's report or testimony, TRS respectfully requests that the Court correct the Magistrate Judge's ruling under Fed. R. Civ. P. 72, deny Defendants' motions entirely, and allow Dr. Gall and Dr. Vanderhart to testify at trial in accordance with their reports.

Dated: June 3, 2020

TRANS-RADIAL SOLUTIONS, LLC

By: */s/ W. Ryan Snow*

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of June 2020, I electronically filed the foregoing document with the Clerk of the Court, using the ECF system of the court. The ECF system will send a "Notice of Electronic Filing" to the attorneys of record who have consented in writing to accept this Notice as service of this document by electronic means.

/s/ W. Ryan Snow

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